Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1192 is amended by revising paragraph (b) to read as follows:

§ 522.1192 Ivermectin injection.

* * * * *

(b) *Sponsors.* See No. 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section. See No. 059130 in § 510.600(c) of this chapter for use as in paragraphs (d)(2), (d)(3), (d)(4), and (d)(6) of this section.

* * * * *

Dated: February 12, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–5222 Filed 3–2–01; 8:45 am]

BILLING CODE 4160–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Pour-On

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for topical use of ivermectin on cattle for treatment and control of various species of external and internal parasites.

DATES: This rule is effective March 5, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861, filed ANADA 200–299 for Ivermectin Pour-On for Cattle. The application provides for topical use of 0.5 percent ivermectin solution on cattle for the treatment and control of various species of gastrointestinal nematodes, lungworms, grubs, horn flies, lice, and mites. Med-Pharmex's Ivermectin Pour-On for Cattle is approved as a generic copy of Merial Limited's IVOMEC® (ivermectin) Pour-On for Cattle, approved under NADA 140–841. ANADA 200–299 is approved as of December 28, 2000, and the regulations in § 524.1193 (21 CFR 524.1193) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 524.1193 is further revised to reflect current format and to reflect the expiration of 3 years of marketing exclusivity granted to Merial Ltd,. in 1997 (62 FR 38907, July 21, 1997), for which revisions were made to § 524.1193 (63 FR 44384, August 19, 1998).

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1193 is amended in paragraph (a) by adding ''(mL)'' after ''milliliter''; by revising paragraph (b); by redesignating paragraph (d) as paragraph (e) and by adding new paragraph (d); and by revising redesignated paragraph (e) to read as follows:

§ 524.1193 Ivermectin pour-on.

* * * * *

(b) *Sponsors.* See Nos. 050604, 051259, and 059130 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use.* (1) *Amount.* One mL per 22 pounds of body weight.

(2) *Indications for use in cattle.* It is used topically for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Oesophagostomum radiatum*; (adults) *O. venulosum*, *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Chorioptes bovis*, *Sarcoptes scabei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalina bovis*, *Solenoptes capillatus*; horn flies *Haematobia irritans.* It is also used to control infections of gastrointestinal roundworms *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.

(3) *Limitations.* Do not treat cattle within 48 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

Dated: February 12, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–5221 Filed 3–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin, Bacitracin Methylene Disalicylate, and Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved, single-ingredient monensin and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds for broiler and replacement chickens. These combination medicated feeds are used as an aid in the prevention of coccidiosis, as an aid in the prevention and control of necrotic enteritis, and for increased rate of weight gain and improved feed efficiency.

DATES: This rule is effective March 5, 2001.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–140 that provides for use of COBAN® (45 or 60 grams per pound (g/lb) of monensin activity as monensin sodium) and BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb bacitracin methylene disalicylate) Type A medicated articles to make combination Type C medicated feeds containing 90 to 110 grams per ton (g/ton) monensin and 4 to 50, 50, or 100 to 200 g/ton bacitracin methylene disalicylate for use in broiler chickens and replacement chickens intended for use as caged layers. The Type C medicated feeds containing 90 to 110 g/ton monensin and 4 to 50 g/ton bacitracin methylene disalicylate are used as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency in replacement chickens intended for use as caged layers. The Type C medicated feeds containing 90 to 110 g/ton monensin and 50 g/ton bacitracin methylene disalicylate are used as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin in broiler chickens and replacement chickens intended for use as caged layers. The Type C medicated feeds containing 90 to 110 g/ton monensin and 100 to 200 g/ton bacitracin methylene disalicylate are used as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin in broiler chickens and replacement chickens intended for use as caged layers. The NADA is approved as of January 2, 2001, and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.355 is amended by adding paragraphs (f)(1)(xxix) and (f)(1)(xxx), by redesignating paragraphs (f)(4)(ii), (f)(4)(iii), and (f)(4)(iv) as paragraphs (f)(4)(iv), (f)(4)(vi), and (f)(4)(vii), and by adding paragraphs (f)(4)(ii), (f)(4)(iii), and (f)(4)(v) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(1) * * *

(xxix) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(xxx) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 100 to 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium spp.* or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

* * * * *

(4) * * *

(ii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 4 to 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 50 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by

E. necatrix, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

* * * * *

(v) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 100 to 200 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(b) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

* * * * *

Dated: February 12, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–5220 Filed 3–2–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin and Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for use of monensin and tylosin single-ingredient Type A medicated articles to make combination drug Type C medicated feeds used for improved feed efficiency, prevention and control of coccidiosis, and reduction of the incidence of liver abscesses in cattle fed in confinement for slaughter.

DATES: This rule is effective March 5, 2001.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 104–646 that provides for use of RUMENSIN® (20, 30, 45, 60, 80, or 90.7 grams per pound (g/lb) monensin activity as monensin sodium) and TYLAN® (10, 40, or 100 g/lb tylosin phosphate) Type A medicated articles to make combination drug Type C medicated feeds for cattle fed in confinement for slaughter. The Type C medicated feeds contain 10 to 30 g/ton monensin and 8 to 10 g/ton tylosin, and are used for improved feed efficiency, prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and reduction of the incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes*. The supplemental NADA is approved as of February 2, 2001, and the regulations are amended in 21 CFR 558.355 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.355 is amended by adding paragraph (f)(3)(xii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(xii) *Amount per ton.* Monensin, 10 to 30 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use.* For improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes*.

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously to provide 50 to 360 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 360 milligrams per head per day; and 60 to 90 milligram of tylosin per head per day.

* * * * *

Dated: February 15, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation Center for Veterinary Medicine.

[FR Doc. 01–5219 Filed 3–2–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05–01–004]

RIN 2115–AE46

Special Local Regulations for Marine Events; Approaches to Annapolis Harbor, Spa Creek, and Severn River, Annapolis, Maryland

AGENCY: Coast Guard, DOT.